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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/578,275	05/05/2006	Masaki Fujiwara	10873.1774USWO	1950

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EXAMINER	
KAUR, GURPREET	

ART UNIT	PAPER NUMBER
1759	

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12/30/2011	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/578,275	FUJIWARA ET AL.	
	Examiner	Art Unit	
	GURPREET KAUR	1759	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 July 2011*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

5)☒ Claim(s) *16-43* is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6)☐ Claim(s) _____ is/are allowed.

7)☒ Claim(s) *16-43* is/are rejected.

8)☐ Claim(s) _____ is/are objected to.

9)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

12)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3/22/2011 and 8/30/2011*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

1. Claims 16-43 are pending in the application.

Continued Examination Under 37 CFR 1.114

2. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7/15/2011 has been entered.

Status of the Rejections

3. New grounds of rejection under 35 USC 103(a) are necessitated in view of applicants' amendments.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. Claims 16, 17, 19, 21-24, 28-33, 35, 37 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Surridge et al. (US Pub No. 2005/0023152) in view of Kuhn et al. (USPN 5,385,846) and Taniike et al (USPN 6,599,407).

Re claims 16, and 17 Surridge et al. teaches a device of determining glucose concentration in blood a redox reaction occurs between the glucose in the blood with enzyme and a mediator (see paragraphs 0041, 0058, 0066 and 0093 and figure 9), the device comprised of :

a first analysis portion comprised of electrode pair (868) on which enzyme (oxidoreductase) that acts on the mediator are provided; and

a second analysis portion in which a Hct value of the blood is measured, comprising a second electrode pair (866) comprising a working electrode and counter electrode (see paragraphs 0069 and 0093);

in the first analysis portion an oxidation current is detected by the electrode pair (868) due to the electrooxidation reaction (see paragraphs 0059 and 0066) and calculating the concentration of glucose based on the detected current value (see equation 1a and paragraphs 0036 and 0037).

in the second analysis portion calculating the hematocrit (Hct) value of the blood and correcting the amount of glucose using the Hct value by applying voltage to the electrode system in the state to cause an oxidation current to flow between the second

electrodes and detecting the oxidation current ; and calculating the Hct value based on the detected current (see paragraphs 0069 and 0093).

Surridge does not explicitly teach in the HCt detection a mediator is present and that the mediator is only disposed only on the counter electrode and not on the working electrode.

However, Kuhn teaches device for detecting Hct wherein a mesh layer comprising mediator (ferrocyanide) is disposed on both the working and counter electrode and potential difference is applied such that diffusion of ferrocyanide at the working electrode is oxidized to ferricyanide and produce oxidation current (see col. 2, ll. 54-60 and col. 4, ll. 13-19). Kuhn further goes on to say that the diffusional event limits the amount of current generated due to the diffusion of ferrocyanide to the surface of the working electrode. Diffusion-limited current is due to the higher concentration of ferricyanide in the blood and reagent mixture than the concentration of ferrocyanide in the blood and the reagent mixture and to overcome such diffusion-limited current, the concentration of ferrocyanide in the reagent mixture is present in sufficient amount to correlate current measurements to the hematocrit level of the blood sample (see col. 4, ll. 47-63). Increasing the amount of ferrocyanide worsens the correlation of current to the hematocrit level once the sample is saturated (see col. 4, ll. 63-68 over to col. 5, ll. 1-2).

Moreover, Taniike et al. teaches a method to overcome the rate determining step by disposing the mediator only on the counter electrode and not on the working electrode such that sufficient concentration of potassium ferricyanide is retained on the

counter electrode and as a result a linear response current can be measured at high substrate concentration (see col. 6, ll. 35-43).

Thus in view of combined teachings of Surridge, Kuhn and Taniike, the mediator is disposed only on the counter electrode and there is no reagent present on the working electrode as taught by Surridge, thus the measured current at the second electrode system is independent of oxidation of the mediator and is only to Hct value of the blood.

Thus in view of Kuhn and Taniike teachings, it would be obvious to one of ordinary skill in the art to modify the Surridge Hct measuring portion by disposing the mediator only on the counter electrode because it would result in linear current response at high substrate concentration and prevents reaction at the counter electrode from becoming a rate determine step.

5. Regarding claim 18, the working electrode and counter electrode in the second electrode system (866) are provided on a same insulating base material so as to be coplanar and spaced apart from each other (see figure 9).

6. Regarding claims 19 and 20, a capillary channel comprising second analysis portion (866) which is on upstream side and first analysis portion 868) is downstream from the flow of the blood and working electrode (first electrode finger) is on an upstream side and counter electrode (second electrode finger) is on a downstream side with respect to flow of the blood supplied from the channel (see figure 9).

7. Regarding claims 21, 22, 31 and 32, Kuhn et al. teaches potassium ferricyanide is used to detect Hct value in the second analysis portion of Surridge (see Kuhn col. 2, ll. 54-60 and col. 4, ll. 13-19).

8. Regarding claims 23 and 24, Taniike et al. teaches working electrode is coated with carboxymethylcellulose (polymeric material) (see paragraphs 0032 and 0037).

8. Regarding claim 28, Surridge et al. teaches first electrode system comprised of working and counter electrodes (see paragraphs 0093 and 0058).

9. Regarding claims 33, 35 and 36, Surridge teaches an insulating substrate (212) comprises electrodes 868 and 866 i.e. first and second analysis portion and capillary channel is formed when the spacer cutout (notch guide, 214) is laid on the substrate, the channel has supply inlet to introduce body fluid (blood) (see paragraph 0093and figure 9). Surridge teaches a capillary channel comprises second analysis portion (electrodes 566) which is on upstream side and first analysis portion (electrodes 868) is downstream from the flow of the blood and a cover (218) is layered on top of the notch guide (see paragraph 0093 and figure 9).

10. Regarding claim 37 and 38, Surridge et al. teaches the component to be measured is glucose as mentioned above and Taniike teaches glucose oxidase is the oxidoreductase (see Taniike col. 6, ll. 17-22).

11. Regarding claims 29 and 30, Surridge teaches first and second analysis portion which are comprised of pair of electrodes (see claim 16 above) and furthermore both the electrodes are made up of platinum or gold which is the same material used in applicant's electrodes (see paragraph 0061). The limitations reciting where one of electrode in the first electrode system serve as counter electrode or working electrode in the second electrode is just an intended use of the electrode in the first electrode system. The cited prior art teaches all of the positively recited structure and material composition of the claimed apparatus. The Courts have held that a statement of intended use in an apparatus claim fails to distinguish over a prior art apparatus. See *In re Sinex*, 309 F.2d 488, 492, 135 USPQ 302, 305 (CCPA 1962). The Courts have held that the manner of operating an apparatus does not differentiate an apparatus claim from the prior art, if the prior art apparatus teaches all of the structural limitations of the claim. See *Ex Parte Mash am*, 2 USPQ2d 1647 (BPAI 1987). The Courts have held that apparatus claims must be structurally distinguishable from the prior art in terms of structure, not function. See *In re Danley*, 120 USPQ 528, 531 (CCPA 1959); and *Hewlett-Packard Co. V. Bausch and Lomb, Inc.*, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990) (see MPEP §§ 2114 and 2173.05(g)).

12. Regarding claim 40, Surridge et al. teaches in a different embodiment to include detection electrode at the end of first and second analysis portions to detect sufficiency

of sample volume has reached in the sample cavity to cover all the electrode pairs (see figure 10 and paragraph 0096).

13. Claims 25-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Surridge, Kuhn and Taniike as applied to claim 16 above, and further in view of Lewandowski et al. (U.S. Pat. No. 4,897,162).

Regarding claims 25-27 Surridge teaches voltage is applied to the Hct electrode system to measure current and Kuhn teaches voltage of 500 mV is applied to electrode system or any voltage can be applied to enable oxidation of electron mediator (see col.4, ll. 7-9).

Both Surridge and Kuhn do not explicitly indicate voltage is 1 to 10 V.

However, Lewandowski teaches a glucose sensing apparatus wherein the pulse voltage of 0.8 to 2.5 Volts can be applied to the electrode system to measure the glucose levels and such variation of applied voltage gives higher catalytic activity, better stability and better control of background current (see col. 5, ll. 3-29).

Therefore it would be obvious to person of ordinary skill in the art at the time of the invention to modify the voltage range applied to electrode system of Surridge as taught by Lewandowski because applied pulse voltage gives higher catalytic activity, better stability and better control of background current (see col. 5, ll. 3-29).

14. Claim 34 is rejected under 35 U.S.C. 103(a) as being unpatentable over Surridge, Kuhn and Taniike as applied to claims 16 above, and further in view of Hsu et al. (U.S. Pub. No. 2004/0134779).

Regarding claim 34, Surridge teaches an insulating substrate (212) comprises electrodes 868 and 866 i.e. first and second analysis portion and capillary channel is formed when the spacer cutout (notch guide, 214) is laid on the substrate, the channel has supply inlet to introduce body fluid (blood) (see paragraph 0093 and figure 9). Surridge teaches a capillary channel comprises second analysis portion (electrodes 566) which is on upstream side and first analysis portion (electrodes 868) is downstream from the flow of the blood (see paragraph 0093 and figure 9).

However, Surridge, Kuhn and Taniike does not teach branched channel with ends of the branched portions communicating with the analysis portion.

However, Hsu et al. teaches a strip for analyzing the sample wherein the channel is branched into two portions and each portion communicates with a different analysis portion encompassing different set of electrode pairs (see paragraphs 0033 and 0034 and figure 4).

Therefore it would be obvious to person of ordinary skill in the art at the time of the invention to modify the arrangements of the electrode and channel shape of Surridge as taught by Hsu i.e. arrange the electrodes parallel across the width of the substrate such that branch channel can reach each analysis portion comprised of different set of electrodes because with such an arrangement different analytes can be measured with a sample (see paragraph 0034).

15. Claim 39 is rejected under 35 U.S.C. 103(a) as being unpatentable over Surridge, Kuhn and Taniike as applied to claim 16 above and further in view of Miyazaki et al. (U.S. Pub. No. 2002/0179442) and Wilsey et al. (U.S. Pat. No. 6,541,216).

Regarding claim 39, Surridge teaches reagent comprised of enzyme and a mediator (see paragraph 0065) applied on the working electrode and Taniike et al. teaches working electrode is coated with carboxymethylcellulose (polymeric material) (see paragraphs 0032 and 0037).

Surridge, Kuhn and Taniike do not teach reagent layer on the first electrode system is comprised of enzyme stabilizer and crystal homogenizing agent.

However, Miyazaki teaches the reagent layer which is disposed on the electrode system is comprised of amino acid which prevents potassium ferricyanide from being crystallized and further helps reagent layer to be formed smoothly and homogeneously (see figure 11 and paragraph 0131).

Therefore it would be obvious to person of ordinary skill in the art at the time of the invention to add amino acid into the reagent layer as taught by Miyazaki into the reagent layer as taught by combined teachings of Surridge and Taniike because amino acid prevents potassium ferricyanide from being crystallized and further helps reagent layer to be formed smoothly and homogeneously (see paragraph 0131).

Surridge, Kuhn, Taniike and Miyazaki do not teach reagent layer on the first electrode system is comprised of enzyme stabilizer.

However, Wilsey et al. teaches test strip wherein the reagent contains stabilizer for the enzyme because stability of the enzyme in turns affects the enzyme's activity which is needed to catalyze the reaction between the mediator and the analyte of interest (see col. 9 ll.6-35).

Therefore it would be obvious to person of ordinary skill in the art at the time of the invention to add enzyme stabilizer into the reagent layer as taught by Wilsey into the reagent layer as taught by combined teachings of Surridge, Taniike and Miyazaki because stabilized enzyme affects the enzyme's activity which is needed to catalyze the reaction between the mediator and the analyte of interest (see col. 9 ll.6-35).

16. Claims 41 and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Surridge, Kuhn and Taniike as applied to claim 16 above, and further in view of Ikeda et al. (U.S. Pat. No. 5,582,697).

Regarding claims 41 and 42, Surridge and Taniike teaches measuring the current of the electrode system by applying voltage (see claim16 above) but do not explicitly indicate the measuring means.

However, Ikeda teaches biosensor (B) is connected to measuring device (A) which holds the biosensor, a current/voltage circuit, an A/D converting circuit for applying voltage and measuring current to the electrodes and a controller 28 including a microcomputer which is capable of calculating and correcting values (see figures 7 and 8).

Therefore it would be obvious to person of ordinary skill in the art at the time of the invention to incorporate the measuring device of Ikeda with Surridge device to apply voltage, measure current, calculate and correct values with the same measuring device (see figures 7 and 8) and moreover make a compact device.

17. Claim 43 is rejected under 35 U.S.C. 103(a) as being unpatentable over Surridge Kuhn, Taniike and Ikeda as applied to claim 41 above, and further in view of Lewandowski et al. (U.S. Pat. No. 4,897,162).

Regarding claim 43, Surridge teaches voltage is applied to the Hct electrode system to measure current and Kuhn teaches voltage of 500 mV is applied to electrode system or any voltage can be applied to enable oxidation of electron mediator (see col.4, ll. 7-9).

Both Surridge and Kuhn do not explicitly indicate voltage is 1 to 10 V.

However, Lewandowski teaches a glucose sensing apparatus wherein the pulse voltage of 0.8 to 2.5 Volts can be applied to the electrode system to measure the glucose levels and such variation of applied voltage gives higher catalytic activity, better stability and better control of background current (see col. 5, ll. 3-29).

Therefore it would be obvious to person of ordinary skill in the art at the time of the invention to modify the voltage range applied to electrode system of Surridge as indicated by Lewandowski because applied pulse voltage gives higher catalytic activity, better stability and better control of background current (see col. 5, ll. 3-29).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 16, 17, 21-27, 37 and 38 provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-8, 14 and 15 of copending Application No.12/829077. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 1 of the co-pending application uses the device comprising an electrode system to detect an oxidation current to measure a component in blood and a second electrode system to detect Hct value of the blood wherein the second electrode system a mediator is present only on the counter electrode but not on the working electrode and such a device is being claimed in the present application in claim 16.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Examiner acknowledges a restriction was issued between a device and method of measuring a component in the blood on 3/16/2010. However, with the applicant's new amendments to the claims the different applications are not consonant with the restriction requirement made by the examiner, since the claims have been changed in material respects from the claims at the time the requirement was made. For example, the divisional application filed includes additional claims not consonant in scope to the original claims subject to restriction in the parent. Symbol Technologies, Inc. v. Opticon, Inc., 935 F.2d 1569, 19 USPQ2d 1241 (Fed. Cir. 1991) and Gerber Garment Technology, Inc. v. Lectra Systems, Inc., 916 F.2d 683, 16 USPQ2d 1436 (Fed. Cir. 1990). In order for consonance to exist, the line of demarcation between the independent and distinct inventions identified by the examiner in the

requirement for restriction must be maintained. 916 F.2d at 688, 16 USPQ2d at 1440 (see MPEP 804.01 (b))

Response to Arguments

Applicant's arguments filed 7/15/2011 have been fully considered but they are moot in view of new grounds of rejection.

Applicant argues on page 8 regarding the measurement of current in Taniike is dependent on the mediator concentration.

Examiner respectfully agrees with applicant's argument, however, combined teachings of Surridge, Kuhn and Taniike, the mediator is disposed only on the counter electrode and there is no reagent (enzyme or mediator) present on the working electrode as taught by Surridge (see figure 9 and paragraph 0093). Furthermore, Surridge also mentions electroxidation or electroreduction of analyte can be done without the redox mediator on the working electrode (see paragraph 0059). Thus the measured current at the second electrode system is independent of oxidation of the mediator and is only to Hct value of the blood.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to GURPREET KAUR whose telephone number is (571)270-7895. The examiner can normally be reached on Monday-Friday 9:00-5:30pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey T. Barton can be reached on (571)272-1307. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/G. K./
Examiner, Art Unit 1759

/Alex Noguerola/

Primary Examiner, Art Unit 1759

December 29, 2011